REMARKS

The Examiner rejected claims 25-26 as being substantial duplicates of present claims 18 and 19, respectfully. Applicant has cancelled claims 25 and 26.

The Examiner has rejected claims 20-22 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Applicant respectfully transverses the rejection. Applicant notes the specification at page 35, line 19 to page 36, line 11 describes various "mono-phasic or multi-phasic OCP regimens" that contain dosages of norgestimate. Thus, the paragraph clearly calls out the use of "multi-phasic OCP regimens." However, while the paragraph specifies the higher dosages of the multi-phasic regimen, it does not explicitly recite the lower dosages in the other phases. Applicant respectfully submits that it would be readily apparent to a person of ordinary skill in the art that the teachings would apply to "multi-phasic OCP regimens" that contain norgestimate, including those norgestimate dosages in multi-phasic regimens that are disclosed in the specification. Applicant notes that those norgestimate dosages in multi-phasic regimens are well known in the art and are taught explicitly on page 6 of the specification. A person skilled in the art would readily understand that where only one dosage is taught for one of the phases, yet the disclosure states that it is useful in "multi-phasic OCP regimens" containing norgestimate, that would be fully applicable to the norgestimate dosages in tri-phasic regimen disclosed on page 6 for norgestimate. Applicant respectfully requests that the Examiner withdraw the rejections of claims 20-22 under 35 U.S.C. §112.

The Examiner has also rejected claims 1-6, 10, 12-15, 17-18 and 24-25 under 35 U.S.C. §102(b) as being anticipated by Pasquale U.S. Patent No. 4,544,554. Applicant has amended claim 1 to require estrogen in the range of at least 20 to less than 35 mcg. Support for this is found in the specification at page 35 lines 28-31. That statement clearly shows that applicant's invention would include the range of 20 to dosage less than 35 mcg. Applicant respectfully

submit that this Amendment eliminates the §102(a) rejection. Pasquale does not teach the higher dosages of norgestimate in combination with this lower estrogen dosage.

Applicant notes that claim 7 has been amended to keep the original range of the 20-35 mcg's Ethinyl Estradiol (EE) of estrogen. Applicant notes that the Pasquale patent does not disclose any daily dosages with at least 1.2 mg of norgestimate.

Applicant has also amended claims 16 and 23. Applicant notes that Pasquale does not disclose regimens which have higher dosages of norgestimate of at least 0.5 or 0.8 mg, with other lower dosages of norgestimate in the range of 0.2-0.3.

The Examiner has also rejected claims 1-26 under 35 U.S.C. §103 as being unpatentable over the Pasquale patent in view of Elliesen. The Examiner has stated that any differences between the claims in Pasquale could be overcome by Elliesen statement that modifications to the progestin dosages are necessary to deal with hormonal fluctuations during menopause. Applicant respectfully submits that there is not even a *prima facie* showing with respect to the proposed combination. Pasquale deals with OCP formulations having generally higher hormonal dosages than the HRT formulations. Elliesen deals with HRT regimens. The Examiner cites a teaching that HRT regimens can be modified because of issues ***during menopause***. But this teaching has nothing to do with OCP formulations of Pasquale.

For the similar reason, applicant respectfully requests that the Examiner remove the double patenting rejection. Elliesen does provide any reason to modify claims 1 and 14 of the '250 patent. One cannot simply point to Elliesen's general teaching of modifications and then conclude that all combination are prima facie obvious. Elliesen is not a motivation to practice infinite modifications. There must be some reason that one would modify Pasquale. There is not one and there is no *prima facie* obviousness.

Please charge any fees associated with this filing to Deposit Account No. 10-0460.

Respectfully submitted,

Raymond N. Nimrod
Registration No. 31,987
Jenner & Block
330 N. Wabash
Chicago, Illinois 60611
312-923-8306